

AMENDMENTS TO THE DRAWINGS:

Please find accompanying this response a replacement sheet for Fig. 4, wherein amendments explained in the Remarks presented below are effected.

REMARKS

Claims 1-10 and 12-24 are now pending in this application. Claims 1-10 and 12-16 are rejected. Claim 11 is previously cancelled. New claims 17-24 are added. Claims 1 and 3 are amended herein to clarify the invention, to express the invention in alternative wording and to address matters of form unrelated to substantive patentability issues.

Applicants herein traverse and respectfully request reconsideration of the rejection of the claims and objection cited in the above-referenced Office Action.

The drawings are objected to because the replacement sheet filed March 2, 2009 does not contain a figure number. A substitute replacement drawing is submitted herewith, and which now correctly indicates the drawing as being Fig. 4. No new matter is added. Entry of the replacement sheet and withdrawal of the objection are respectfully requested.

Claims 1-8 and 13-15 are rejected under 35 U.S.C. § 102(b) as being anticipated by Edelman et al. (US 4,814,144). Applicants herein respectfully traverse these rejections. "Anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, *arranged as in the claim.*" *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 221 USPQ 481, 485 (Fed. Cir. 1984) (emphasis added). It is respectfully submitted that the cited reference is deficient with regard to the following.

Independent claim 1 is amended, and recites in pertinent part the following:

the separation cell having an internal structure including a lower portion that defines an insoluble matter collection zone and an upper portion that defines a supernatant separation zone, the horizontal sectional area of the supernatant separation zone being greater than the sectional area corresponding to the insoluble matter collection zone such that a shelf is formed at the boundary between the supernatant separation zone and the insoluble matter collection zone

It is respectfully submitted that no such structural configuration is taught or suggested in the cited Edelmann et al. reference. The positional relationship between the "insoluble matter collection part 7" and the "supernatant separation part 8" in the present invention is entirely different from the positional relationship between the part in which solid components (insoluble matter) in the blood are collected (corresponding to the "insoluble matter collection part 7" in the present invention) and the part where the separated serum or plasma (supernatant) is received (the part which is filled, corresponding to the "supernatant separation part 8" in the present invention).

Specifically, in Edelmann et al., these parts are disposed in the crosswise direction (horizontal direction) (see, for example, column 12, lines 32 to 37), while, in the present invention as claimed in claim 1, the "insoluble matter collection part 7" and the "supernatant separation part 8" are disposed in the vertical direction (perpendicular to crosswise direction) (see for example paragraph [0044] of the published present application and FIG. 3). In accordance with the separation cell of the presently claimed invention of claim 1, separation is performed in the direction that is perpendicular to the direction in which the centrifugal force acts. In stark contrast, in Edelmann et al., the arrangement is such that separation is performed in the direction that the centrifugal force acts, in the same manner as an ordinary conventional separation cell.

Additionally, applicants respectfully submit that a shelf structure, such as that recited in claim 1 as amended, is never even suggested in the Edelmann et al. separation cell. In stark contrast thereto, in the separation cell of the present invention of claim 1, the supernatant and the insoluble matter are separated in the vertical direction (direction perpendicular to the direction in which the centrifugal force acts) and therefore a "shelf" structure of this sort is necessary. In accordance with Edelmann, as in an ordinary conventional separation cell, the separation is performed in the crosswise direction (horizontal direction in which the centrifugal force acts), and therefore a structure of this sort is not necessary, and hence, not disclosed.

In view of the above, it is respectfully submitted that claims 1-8 and 13-15 particularly describe and distinctly claim elements not disclosed in the cited reference. Therefore, reconsideration of the rejections of claims 1-8 and 13-15 and their allowance are respectfully requested.

Claims 9-10, 12 and 16 are rejected under 35 U.S.C. § 102(b) as being anticipated by Anderson (US 6,346,421). Applicants herein respectfully traverse these rejections.

The separation cell of the present invention of claim 9 is "disposed substantially parallel to the rotational axis." Conversely, the separation cell disclosed in FIG. 3F of Anderson is disposed on a "slanted" orientation. Thus, applicants respectfully submit that the present invention of claim 9 and Anderson have completely different structures.

Additionally, as is clear from Figs. 1-3, 5 and 6, etc. of the present application, the lid 6 of the present invention only covers a portion of the top of the cell. As a matter of course, this state does not change during centrifugation, i.e, in accordance with the claimed invention of claim 9, a portion of the top of the cell remains open during centrifugation.

Conversely, in Anderson et al., as is clear from column 14, line 44 to column 15, line 12 and Figs. 9A to 9F, the top of the cell (tube) is covered by an "annular seal (ring) 151" having a "central hole" into which a plug can be inserted and removed (FIG. 9A, etc.). However, the "central hole" of this annular seal (ring) 151 is sealed

by being closed by a "plastic countersunk screw 160" when centrifugation is performed and the opening at the top of the cell (tube) is no longer present, as it is in the present invention (see column 14, lines 58 to 60 and Figs. 9C, 9D of Anderson et al.). Thus, such a lid 6 of the present invention and the annular seal (ring) 151 and plastic countersunk screw 160 of Anderson et al. are completely different, structurally.

Furthermore, the separation cell of the present invention "is disposed substantially parallel to the rotational axis and is also held in said substantially parallel direction during centrifugation." Thus, in the invention of claim 9, the cell is in an upright state, not only when at rest, but also during centrifugation.

Conversely, the separation cell disclosed, and as shown in Fig. 3F of Anderson, is disposed slanted and is slanted during centrifugation as well. Furthermore, the separation cell disclosed in Fig. 4B is in a "horizontal state (perpendicular to the rotational axis)" during centrifugation. This is clear from column 9, lines 37 to 40 and lines 52 to 53; column 10, lines 5 to 7; column 14, lines 21 to 22 and Fig. 3F and 4B of Anderson.

Regarding claim 10, it is the Examiner's position that the Examiner has found that the "shelf" structure in claim 10 of the present invention is also present in the Anderson cell. However, applicants respectfully submit that the examiner has failed to acknowledge structural distinctions.

In particular, the separation cell of the present invention is such that (1) the separation cell (at the least inner wall at the radially outward side) is substantially parallel to the rotational axis (i.e., in the upright state during centrifugation as well as at rest); and (2) has a "shelf" structure that extends horizontally towards the center of rotation. As such, the separation cell of the present invention is such that (1) a vertical inner wall of the separation cell substantially perpendicularly crosses (is orthogonal to) (2) the "shelf" structure (horizontal plane). Conversely, the separation cell of Anderson et al., shown for example in Fig. 3F of the reference, which is referred to by the Examiner, is such that the separation cell itself is not in the upright state and thus the inner wall of the separation cell and the "shelf" structure are not orthogonal.

Furthermore, the separation cell in Fig. 4B of Anderson is not only such that the separation cell itself is not in the upright state, but the "shelf" structure itself is not horizontal and these are not orthogonal.

Even if the separation cell of Anderson were to be placed in the upright state, because the "shelf" structure is not horizontal, this too would not constitute the structure of the separation cell of the present invention. (For example, see Fig. 3A-3E and 3G.) With the "shelf" structure inclined in this manner, there is no function whereby disturbance of the insoluble matter is prevented when the supernatant is collected with the pipette. This function according to the present invention can only be provided when only supernatant is present above the shelf.

In view of the above, it is respectfully submitted that claims 9-10, 12 and 16 particularly describe and distinctly claim elements not disclosed in the cited reference. Therefore, reconsideration of the rejections of claims 9-10, 12 and 16 and their allowance are respectfully requested.

Claims 17-25 are added and are submitted as patentable over the cited art of record. Independent claim 23 recites subject matter directed to at least one separation cell having an internal structure defining an insoluble matter collection zone in a lower portion of said at least one separation cell and a supernatant separation zone in an upper portion of the separation cell, a horizontal sectional area of the supernatant separation zone being greater than another horizontal sectional area corresponding to the insoluble matter collection zone and such that a shelf is formed at the boundary between the supernatant separation zone and the insoluble matter collection zone where a portion of said supernatant separation zone extends radially inward of the insoluble matter collection zone, said shelf being comprised of a horizontally extended ledge which is orthogonal to a radially inward vertical wall of the insoluble matter collection zone, the separation cell including a lid being positioned to only partially cover each said at least one separation cell, and being disposed at a radially outward position of separation cell directly over the sectional area corresponding to the insoluble matter collection zone, so as to leave an opening through which the supernatant is withdrawable from above the portion of the

supernatant separation zone which extends radially inward of the insoluble matter collection zone, while concomitantly blocking flow of the suspension outward from the separation cell during centrifugal separation which, among other features recited therein, is not believed disclosed in the cited art in the manner as claimed. Dependent claims 17-22 and 24 are patentable based on the subject matter recited therein in addition to the subject matter of the claims from which they depend.

Five (5) claims in excess of twenty are added. **The fee of \$260 for the claims is provided for in the charge authorization presented in the PTO Form 2038, Credit Card Payment form, provided herewith.**

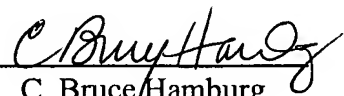
Applicants respectfully request a two (2) month extension of time for responding to the Office Action. **The fee of \$490 for the extension is provided for in the charge authorization presented in the PTO Form 2038, Credit Card Payment form, provided herewith.**

If there is any discrepancy between the fee(s) due and the fee payment authorized in the Credit Card Payment Form PTO-2038 or the Form PTO-2038 is missing or fee payment via the Form PTO-2038 cannot be processed, the USPTO is hereby authorized to charge any fee(s) or fee(s) deficiency or credit any excess payment to Deposit Account No. 10-1250.

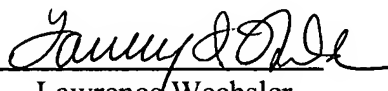
In light of the foregoing, the application is now believed to be in proper form
for allowance of all claims and notice to that effect is earnestly solicited.

Respectfully submitted,

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Enc: Form PTO-2038; and Replacement sheet of Fig. 4.